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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,076	07/24/2003	Andrea Venturelli	71067	4532

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WASHINGTON, DC 20004

EXAMINER

MEHTA, BHISMA

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

6D

Office Action Summary	Application No. 10/626,076	Applicant(s) VENTURELLI, ANDREA	
	Examiner Bhisma Mehta	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/311,498.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/311,498, filed May 13 1999. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is

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considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the main tube distal end as having a lateral opening and also fails to disclose the main tube as having a lateral opening edge.

Claim Objections

3. Claims 5 and 17 are objected to because of the following informalities: In claim 5, it appears that "distal tubes" in line 2 should be "distal tube". Claim 17 recites the limitation "the lateral opening edge" in line 3. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5-7 and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 5 and 13, the use of "said lateral opening of said guide tube" is unclear, as the guide tube has not been established as having a lateral opening. In claims 6 and 14, it is unclear which tubes are being referred to with the use of "said two tubes" in line 2 as a main tube, a distal tube, and a guide

tube have all been established. In claim 7, the use of "a first lumen" for inflation and "a second lumen" for a guide thread is unclear, as "a lumen for a guide thread" has already been recited in line 2 of claim 2.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4-15, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith (U.S. Patent No. 5,156,594). In Figure 2, Keith shows a catheter structure or side port assembly having a main tube (22), a distal tube (82), a guide tube (80), and a balloon (38). In Figure 7, Keith shows the section of the catheter structure or side port assembly having a main tube (22C), a distal tube (82C), and a guide tube (80C). The main tube (22C) is formed from multiple tube sections (64C, 66C). A portion of the guide tube (80C) extends into the distal tube (82C) and a portion of the guide tube (80C) adjacent to the proximal end (100C) of the distal tube is located adjacent to the distal end (shown at 66C) of the main tube. The guide tube (80C) has an opening at the proximal end (92C) of the guide tube on one side of the main tube (22C). A portion of the distal tube (82C) adjacent to the proximal end (100C) of the distal tube encloses both a portion of the distal end of the main tube and a portion of the guide tube. The proximal end of the guide tube extends into a lateral opening (119) of

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the main tube and into the distal tube. Keith also shows an inflation or first lumen (62C, 125, 104C) and a lumen (52C) for a guide thread. In Figure 2, a portion of the proximal end (100) of the distal tube (82) is flared. Keith teaches joining or sealing the ends of the different parts of the catheter structure by suitable means such as by a solder joint which is a form of heat sealing. The proximal ends of the guide tube and the distal tube are beveled at the lateral opening as seen in the figures. The multiple sections of the main tube have different material compositions, different thicknesses, and different rigidities and Keith teaches that the guide tube and the distal tube are formed from materials different than that of the main tube. In line 31-33 of column 7, Keith teaches that the guide tube and the distal tube may be formed of the same material or from materials different from one another. Keith discloses the method for manufacturing the catheter structure as claimed.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith in view of Willard et al (U.S. Patent No. 6,309,379). Keith discloses the catheter structure substantially as claimed. Even though Keith shows a part of the distal end (72) of the main tube (22) which is deflected and inclined towards an inside of the

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main tube, Keith is silent on the proximal end of the guide tube resting on the outside of the inclined part of the main tube. It should be noted that Keith shows the edge of the lateral opening (119) of the main tube (22) in Figure 7 which can also be considered to be deflected and inclined towards an inside of the main tube. Willard et al disclose a balloon catheter structure in the same field of endeavor. In Figure 10, Willard et al show a proximal end of a guide tube (102) located in a lateral opening (50) of a main tube (10) where a part of the main tube is deflected and inclined toward an inside of the main tube and where the proximal end of the guide tube rests on the outside of the inclined part of the main tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to extend the guide tube of Keith such that the proximal end of the guide tube rests on the outside of the inclined part of the main tube as taught by Willard et al as Willard et al teach that it is well known to provide a portion of the guide tube that extends out of the lateral opening and rests on a part of the main tube so that a guide thread or guide wire can be more easily manipulated during a surgical procedure.

10. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith in view of Zarbatany et al (U.S. Patent No. 6,030,405). Keith discloses the method for manufacturing the catheter structure substantially as claimed. However, Keith is silent on the insertion of expanders into the distal end of the main tube and the proximal end of the guide tube during the heat-sealing operation. Zarbatany et al teach inserting expanders into the ends of tubes that will become a lumen for a guide thread or an inflation lumen and removing the expanders after use in the same field of

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endeavor of using heat-sealing to join the different sections of a catheter structure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the lumens of Keith by using expanders as taught by Zarbatany et al as Zarbatany et al teach that it is well known to use expanders to form lumens when using heat-sealing to form a catheter structure.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,635,029.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are all drawn to a rapid exchange catheter.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

